



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/487,558	01/19/2000	Robert Busby	109272.130	3300

7590 07/29/2002

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EXAMINER

DAVIS, KATHARINE F

ART UNIT PAPER NUMBER

1636

DATE MAILED: 07/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/487,558

Applicant(s)

BUSBY ET AL.

Examiner

Katharine F. Davis

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 June 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.


Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-28, 102 and 103.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments presented in the Response filed on June 6, 2002 have been carefully considered but have not been found to be persuasive. Applicants argue that an inventor does not need to know or describe the mechanism of action of an invention to satisfy either the written description or enablement requirement of 112, first paragraph. Applicants further argue that the instant specification and additional declaration of Dr. Todd Milne show several successful experiments. However the scope of the instant claims encompasses any genetic manipulation of any metabolic pathway resulting in overproduction of any secondary metabolite in any fungal species. Are the genes which are modified in the experiments part of a regulatory pathway of secondary metabolism or not? Can all the genes and pathways be assumed to function similarly in all fungal species? Applicants have not provided a nexus between the modified genes and involvement of the modified genes in secondary metabolism. How would one of skill in the art know which genes direct the production of which secondary metabolite in which fungal species? Without answers to these questions one of skill in the art would not even know where to begin modification to improve secondary metabolite production and would result to "trial and error" experimentation in order to practice the invention in the entire scope. This constitutes undue experimentation. Applicants argue that the author of the article cited, S. Parekh, is not skilled in the art of molecular biology of fungi and further state that the article focuses on traditional methods of strain improvement (random mutagenesis and screening). However, these "traditional techniques" are part of molecular biology. Furthermore, the article was cited in the Final Office Action to evidence the complexity of secondary metabolism in fungi. For example, "...the overproduction of secondary metabolites is significantly more complex (than primary metabolism) due to the global cellular regulation of differentiation and antibiotic production." See Parekh et al. page 289. For both of the reasons above and the reasons made of record in the previous Office Actions the rejections of claims 1-28, 102 and 103 under 35 U.S.C. 112, first paragraph (written description and scope of enablement) are maintained.

  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/487558	1-19-00	Busby et al.	mic-001US1

EXAMINER	
K. Davis	
ART UNIT	PAPER NUMBER
1636	24

DATE MAILED:

INTERVIEW SUMMARY

All participants (applicant, applicant's representative, PTO personnel):

(1) Katharine Davis (3) Wayne Keown  
(2) Remy Yucel (4)

Date of Interview May 28, 2002

Type: ☐ Telephonic ☐ Televideo Conference ☒ Personal (copy is given to ☐ applicant ☒ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No If yes, brief description:

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: all pending claims (1-28, 102, 103)

Identification of prior art discussed: no prior art was discussed

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Discussed Final Rejection mailed 3-6-02, discussed  
draft "request for re-consideration". Discussed Standards  
(Legal) for enablement and written description

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary. A FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

Examiner Note: You must sign this form unless it is an attachment to another form.

*Remy Yucel*